Claims

1. A method for determining the prognosis of a patient with breast cancer, the method comprising assigning a prognosis to the patient based on the expression levels in a breast tumour of said patient of a prognostic set of genes, wherein the prognostic set includes at least 5 genes from Table S6.

2. A method according to claim 1, wherein the prognostic set comprises at least 10, 20, 30, 40, 50, 60 or all of the genes of Table S6.

3. A method according to claim 1 or claim 2, further comprising the step of determining the estrogen receptor (ER) status of the tumour sample.

4. A method according to claim 3, further comprising determining the ErbB2 status of the tumour sample.

5. A method according to any one of claims 1 to 4 comprising the steps of:

(a) obtaining a breast tumour sample from the patient; and

(b) measuring the expression levels in the sample of the genes of the prognostic set.

6. A method according to claim 5 wherein step (b) comprises contacting said expression products obtained from the sample with a plurality of binding members capable of binding to expression products that are indicative of the expression of genes of the prognostic set, wherein such binding may be measured.

7. A method according to claim 6 wherein the binding members are complementary nucleic acid sequences or specific antibodies.

8. A method according to any one of claims 1 to 7, comprising classifying the sample of breast tumour as being of either high NPI or low NPI, or as either of good or bad prognosis.

9. A method according to any one of claims 1 to 8, wherein the step of assigning a prognosis is carried out by comparing the expression profile from the breast tumour sample under test with previously obtained profiles and/or a previously determined standard profile which is characteristic of a particular prognosis.

10. A method according to claim 9 wherein the previously obtained profiles are stored as a database of profiles.

11. A method according to any one of claims 1 to 10, further comprising comparing the expression levels of the prognostic set in the breast tumour sample before and after treatment to detect a change in the expression profile indicative of an improved prognosis or worsened prognosis.

12. Apparatus for assigning a prognosis to a breast tumour sample, which apparatus comprises a solid support to which are attached a plurality of binding members, each binding member being capable of specifically and independently binding to an expression product of one of a prognostic set of genes, wherein the prognostic set includes at least 5 genes from Table S6.

13. Apparatus according to claim 12, wherein the prognostic set comprises at least 5, 10, 20, 30, 40, 50, 60 or all of the genes of Table S6.

14. Apparatus according to claim 12 or claim 13 wherein the solid support has attached thereto only binding members that are capable of specifically and independently binding to expression products of the genes identified in Table S6.

15. Apparatus according to any one of claims 12 to 14, comprising a nucleic acid microarray wherein the binding members are nucleic acid sequences.

16. A kit for assigning a prognosis to a patient with breast cancer, said kit comprising a plurality of binding members capable of specifically binding to expression products of genes of a prognostic set of genes and a detection reagent, wherein the prognostic set includes at least 5 genes from Table S6.

17. A kit according to claim 16, wherein the prognostic set comprises at least 10, 20, 30, 40, 50, 60 or all of the genes of Table S6.

18. A kit according to claim 16 or claim 17, further comprising a data analysis tool, wherein the data analysis tool is a computer program.

19. A kit according to claim 18 wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses.

20. A kit according to any one of claims 16 to 19 comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles characteristic of a particular prognosis.

21. A kit according to any one of claims 16 to 20, comprising apparatus according to any one of claims 12 to 15.

22. A kit according to any one of claims 16 to 20, comprising nucleotide primers capable of binding to the expression products of the genes of the prognostic set such that they can be amplified in a PCR.

23. A method of producing a nucleic acid expression profile for a breast tumour sample comprising the steps of

(a) isolating expression products from said breast tumour sample;

(b) identifying the expression levels of a prognostic set of genes, wherein the prognostic set of genes comprises at least 5 genes from Table S6; and

(c) producing from the expression levels an expression profile for said breast tumour sample.

24. A method according to claim 23, wherein the prognostic set comprises at least 10, 20, 30, 40, 50, 60 or all of the genes of Table S6.

25. A method according to claim 23 or claim 24 comprising adding the expression profile to a gene expression profile database.

26. A method according to any one of claims 23 to 25 further comprising comparing the expression profile with a

second expression profile or a plurality of second expression profiles characteristic of a particular prognosis.

27. A method according to claim 26, comprising the steps of:

(a) isolating expression products from a first breast tumour sample; contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set; and creating a first expression profile from the expression levels of the prognostic set in the tumour sample;

(b) isolating expression products from a second breast tumour sample of known prognosis; contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of step (a), so as to create a comparable second expression profile of a breast tumour sample;

(c) comparing the first and second expression profiles to determine the prognosis of the first breast tumour sample.

28. An expression profile database comprising a plurality of gene expression profiles of breast tumour samples, wherein the gene expression profiles are derived from the expression levels of a prognostic set of genes, wherein the prognostic set of genes comprises at least 5 genes from Table S6, which database is retrievably held on a data carrier.

29. An expression profile database according to claim 28, wherein the prognostic set comprises at least 10, 20, 30, 40, 50, 60 or all of the genes of Table S6.

30. An expression profile database according to claim 28 or claim 29, wherein the expression profiles are nucleic acid expression profiles.

31. An expression profile database according to any one of claims 28 to 30, wherein the expression profiles are categorised according to the ER status of the source tumour.

32. A method for identifying a set of genes that are differentially expressed within a group of tumours, the method including providing an expression profile from each of a plurality of tumours of the group, classifying the profiles according to molecular subtype of tumour, and analysing expression profiles within a subtype to identify a discriminating set of genes, wherein the genes of the discriminating set are differentially expressed within that subtype.

33. A method according to claim 32 further comprising steps to assign a class to a tumour sample from a patient, wherein differential expression of genes of the discriminating set are characteristic of the class, the steps including providing expression levels in the sample of the discriminating set, and assigning a class to the tumour based on the expression levels.

34. A method according to claim 32 or claim 33 comprising the steps of determining the expression levels of the genes of the discriminating set in a tumour sample,

determining an expression profile from the expression levels and adding the profile to a database.

35. A method according to any one of claims 32 to 34 wherein the molecular subtype of the tumour sample is also identified and added to the database.

36. A method according to any one of claims 32 to 35 comprising providing expression profiles from the tumour at different stages of treatment and said expression profiles to determine a change in prognostic class, wherein the expression profiles are derived from the expression levels of genes of the discriminating set.

37. A method according to any one of claims 32 to 36 wherein the tumours are breast tumours and the molecular subtype corresponds to the ER status of the tumour.